



#3552212-7-00-01*

MEDICAL PRODUCTS REPORTING PROGRAM

OLUNTARY reporting
by professionals of adverse
events and product problems

Page _____ of _____

CDER

CER

CONFIDENTIAL

127479

Patient information

Patient identifier 6549	2 Age at time of event: 65	3 Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 65 kg
-----------------------------------	---	--	------------------------------

B Adverse event (or product problem)

 Adverse event and/or Product problem (e.g., device malfunction)

- Outcomes attributed to adverse event (check all that apply)
- disability
 - congenital anomaly
 - required intervention to prevent permanent impairment/damage
 - pain
- 1 death _____
1 life-threatening _____
Hospitalization - initial or prolonged _____

Date of event
10/2/98 6. Date of this report
10/5/98

Describe event or problem

Pt admitted for diffuse abdominal pain and presumed cholangitis. Pt drinks 8 beers QD x 40 yrs. Given percocet for back pain from a work related injury. Pt also taking OTC tylenol - total dose approx 4 gm/day. Developed hepatic failure requiring ICU transfer, lactulose, vitamin K. Meconest given empirically.

	AST	ALT	INR
Relevant test/laboratory data, including dates			
10/1/98	199	1125	1.45
10/7/98	451	1969	3.3
10/5/98	3880	4030	6.63
10/2/98	533	1035	1.87

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic renal dysfunction, etc.)

CAD - M2, CAFs, DM, BP11, T cholesterol,
CHF, LTOH

-TUL127479

Severity: **Aware**Probability: **Probable**

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-6178

C Suspect medication(s)

1. Name, give labeled strength & indicate if known

tylenol / percocet

#2

2. Dose, frequency & route used

~ 4 gm QD

#2

3. Therapy dates (if unknown, give duration)

9/1/98-present

#2

4. Diagnosis for use (indication)

back pain

#2

5. Let's (if known)

#1

#2

6. Exp. date (if known)

#1

#2

7. NDC (for product problems only)

#1

#2

10. Concomitant medical products and therapy dates (exclude treatment of event)

D Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- health professional
 - lay user/patient
 - other

RECEIVED

AUG 17 2000

model #

catalog # **MEDWATCH CTU**

serial #

lot #

other #

5. Expiration date (if any)

6. If implanted, give date (if any)

7. If explanted, give date (if any)

8. Device available for evaluation? (Do not send to FDA)

 yes no returned to manufacturer on _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

DSS

E Reporter (see confidentiality section on back)

1. Name, address & phone #

Harold

Baltimore VAMC

10 North Greene Street

Baltimore, Maryland 21201

AUG 18 2000

2. Health professional?

 yes no

3. Occupation

Clinical Pharmacist

4. Also reported to

- manufacturer
- user facility
- distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box



3552212-7-00-02

Probability Scale

(Naranjo, CA et al. CPT 1981;30:239-45)

To assess the adverse drug reaction, please answer the following questionnaire
 & circle the pertinent score

	YES	NO	DO NOT KNOW	SCORE
1. Are there previous <u>conclusive</u> reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse reaction improve when the drug was discontinued or a <u>specific</u> antagonist was administered?	+1	-1	0	
4. Did the adverse reaction appear when the drug was readministered?	+2	-1	0	
5. Are there any alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	
8. Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	
9. Did the patient have a similar reaction to the same or similar drugs in <u>any</u> previous exposure?	+1	0	0	
10. Was the adverse reaction confirmed by objective evidence?	+1	0	0	

TOTAL SCORE

CLASSIFICATION OF ADVERSE DRUG REACTION

Please circle appropriate probability category

1. Definite ≥ 9

2. Probable 5-8

3. Possible 1-4

4. Doubtful ≤ 0

ADR ID CODE:

APR 1981